Doxa

K100510

13 510(k) Summary

MAR 25 2010

13.1 Submitter and manufacturer

Doxa Dental AB
Axel Johanssons gata 4-6
SE 754 51, Uppsala, Sweden
Phone: +46 18 478 000:
Fax: +46 478 001

Contact:
Margareth Jorvid,
Doxa Dental AB,
Axel Johanssons gata 4-6
SE 754 51, Uppsala, Sweden
Phone: +46 70 519 2640
Fax: +46 18 478 2001
E-mail: Margareth.jorvid@lsmgroup.se

13.2 Date of Submission

February 18th, 2010

13.3 Device Name

Trade name
Ceramir® Crown & Bridge

Common or Usual Name
Dental Cement

Classification name

Dental cement other than zinc oxide-eugenol (21 CRF 872.3275)

Product Code

EMA

13.4 Predicate Devices

Trade name	510(k) holder	510(k) No.
XeraCem™	Doxa Dental AB	K081405

13.5 Indications for Use

Ceramir Crown & Bridge is intended for the permanent cementation of

- Porcelain Fused to Metal Crowns and Bridges
- Metal (gold etc.) crowns and bridges
- Gold inlays and onlays
- Cast or prefabricated metal posts

- Strengthened core all-zirconia or all-alumina ceramic crowns and bridges

13.6 Technological characteristics

Ceramir Crown & Bridge is a hybrid glass ionomer-ceramic dental cement. The liquid and powder are packed are in a capsule format. The capsule is activated and the powder and liquid is mixed in a mixer before use.

13.7 Performance Data

Ceramir Crown & Bridge is technologically identical to its predicate device. The powder and liquid are identical. The proportion between amount of powder and amount of liquid is the same in the mixed cement. The packaging format and mixing differs; XeraCem is hand mixed while Ceramir Crown & Bridge is packed and mixed in a capsule format. Studies have proven the properties, including biocompatibility of the cement to be substantially equivalent to the predicate device.

13.8 Substantial Equivalence

Ceramir Crown & Bridge is as safe and effective as the predicate device and performs as well as the predicate device. Ceramir Crown & Bridge has the same intended use and technological characteristics as its predicate device.

In summary, the dental luting cement Ceramir Crown & Bridge described in this submission is, in our opinion, substantially equivalent to the predicate device, XeraCem.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Margareth Jorvid
Regulatory Affairs
Doxa Dental AB
Axel Johanssons, Gata 4-6
Uppsala
Sweden SE-754 51

MAR 2 5 2010

Re: K100510
Trade/Device Name: Ceramir Crown & Bridge
Regulation Number: 21CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: March 19, 2010
Received: March 22, 2010

Dear Ms. Jorvid:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K100510

16.4 Attachment 4: Indications for Use, Ceramir Crown & Bridge

Indications for Use, Ceramir Crown & Bridge

510(k) Number:

Device Name: Ceramir Crown & Bridge

Indications for Use:

Ceramir Crown & Bridge is intended for the permanent cementation of

- Porcelain Fused to Metal Crowns and Bridges
- Metal (gold etc.) crowns and bridges
- Gold inlays and onlays
- Cast or prefabricated metal posts
- Strengthened core all-zirconia or all-alumina ceramic crowns and bridges

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert DDS for Dr KP Mulay

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K100510